

36. An apparatus for detecting nucleic acids in a sample, the apparatus comprising an integrated device comprising:

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- (a) a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities,
 - (b) an amplification space for amplifying the nucleic acids comprising at least part of the binding space, and
 - (c) a detection space for detecting the nucleic acids.

REMARKS

Claims 36-41 and 68 are pending in the application. Claims 42-67 were previously withdrawn from consideration pursuant to a Restriction Requirement. Claim 36 has been amended. Support for the amendment can be found throughout specification, for example, page 11, lines 5-8 and page 12, lines 4-5. No new matter has been added.

Applicants thank the Examiner for her consideration of the Applicants previous arguments and the withdrawal of all the previous rejections.

All of the claims stand rejection under 35 U.S.C. §102(e) as anticipated by Furcht *et al.* (U.S. Patent No. 6,054,277). Applicants respectfully traverse.

Claim 36 has been amended to reflect that the device of the invention is an integrated device. As described in the specification, the detection of nucleic acids is accomplished in this closed device such that binding as well as amplification of the nucleic acids are carried out in the same space. Therefore, the device of the invention is characterized by a simple set-up as well as by easy performance of the detection

procedure. With the device, losses of sample that may lead to false negative results, and contamination of the sample that may lead to false positive results, are eliminated.

On the other hand, the testing system according to Furcht *et al* comprises several components that are combined only in the course of the detection procedure. According to Furcht *et al.*, a FTA matrix collection device (Fig. 1, No. 11) is contacted with the sample and DNA is immobilized on the matrix (col. 8, line 30 – col. 9, line 42). The collection device is then inserted into the sample access port of the gene test card (Fig. 1, No. 14, and column 9, lines 24 - 43). Following amplification of the sample on the gene test card, the sample is transported into a detection chamber via an interconnecting transport capillary on the gene test card where detection is carried out (col. 10, lines 27 - 54).

Thus, contrary to integrated device of claim 36, the testing system according to Furcht *et al.* is not an integrated device but an apparatus comprising several components which are combined only in the course of the testing procedure. This system is not only more complicated than the present invention, but its use involves a risk of contamination and, thus, false positive results. Accordingly, Furcht *et al.* does not teach each and every element of claim 36.

Turning now to claim 68, contrary to the Examiner's conclusion, Furcht *et al.* does not teach an apparatus for amplifying nucleic acids comprising a capillary reaction vessel surrounded by a heatable metal layer that is coated on the vessel. Instead, Furcht *et al.* teach "two opposed, spaced apart microchip heaters" that define part of an amplification chamber (col. 9, lines 47 - 50). The heaters are approximately up to 1 cm square and are components to the top and bottom face wafers of the genetic test

card (col. 9, lines 54 - 56). Clearly, the square, opposed microchips of Furcht *et al.* are not a capillary reaction vessel surrounded by a heatable metal layer that is coated on the vessel as in claim 68. Accordingly, Furcht *et al.* does not teach each and every element of claim 68.

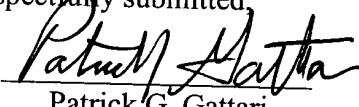
Because Furcht *et al.* does not teach each and every element of claims 36 and 68, Furcht *et al.* does not anticipate claims 36 and 68, or any of the claims that depend from claim 36, under 35 U.S.C. §102(e). Accordingly, Applicants request that this rejection be withdrawn.

CONCLUSION

With the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance. If Examiner is of the opinion that a telephone conference with expedite prosecution of the application, Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted,

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APPENDIX A

Serial No.: 09/780,206
Inventor: Michael Fritz
Attorney Docket No.: 01-1096

Marked up version of amended claim to show changes made

36. An apparatus for detecting nucleic acids in a sample, the apparatus comprising an integrated device comprising:
- (a) a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities,
 - (b) an amplification space for amplifying the nucleic acids comprising at least part of the binding space, and
 - (c) a detection space for detecting the nucleic acids.

APPENDIX B

Serial No.: 09/780,206
Inventor: Michael Fritz
Attorney Docket No.: 01-1096

A clean copy of pending claims

36. An apparatus for detecting nucleic acids in a sample, the apparatus comprising an integrated device comprising:
- (a) a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities,
 - (b) an amplification space for amplifying the nucleic acids comprising at least part of the binding space, and
 - (d) a detection space for detecting the nucleic acids.
37. The apparatus of claim 36 further comprising reagents for purifying, amplifying and detecting the nucleic acid.
38. The apparatus of claim 36, wherein the detection space comprises a part of at least one of the amplification space and the binding space.
39. The apparatus of claim 36, wherein at least one of the binding space and the amplification space comprises a capillary space.
40. The apparatus of claim 39 wherein the capillary space is a capillary reaction vessel surrounded by a heatable metal layer.
41. The apparatus of claim 39 wherein the capillary space is glass or polystyrene.
68. An apparatus for amplifying nucleic acids comprising a capillary reaction vessel surrounded by a heatable metal layer wherein the layer is coated on the capillary reaction vessel.

APPENDIX B

Serial No.: 09/780,206
Inventor: Michael Fritz
Attorney Docket No.: 01-1096

A clean copy of pending claims

36. An apparatus for detecting nucleic acids in a sample, comprising:
 - (a) a binding space for purifying the nucleic acids by immobilizing the nucleic acids and separating impurities,
 - (b) an amplification space for amplifying the nucleic acids comprising at least part of the binding space, and
 - (c) a detection space for detecting the nucleic acids.
37. The apparatus of claim 36 further comprising reagents for purifying, amplifying and detecting the nucleic acid.
38. The apparatus of claim 36, wherein the detection space comprises a part of at least one of the amplification space and the binding space.
39. The apparatus of claim 36, wherein at least one of the binding space and the amplification space comprises a capillary space.
40. The apparatus of claim 39 wherein the capillary space is a capillary reaction vessel surrounded by a heatable metal layer.
41. The apparatus of claim 39 wherein the capillary space is glass or polystyrene.
68. An apparatus for amplifying nucleic acids comprising a capillary reaction vessel surrounded by a heatable metal layer wherein the layer is coated on the capillary reaction vessel.